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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,368	02/28/2002	Andreas Meudt	2001DE305	6588
25255	7590 11/25/2003	EXAMINER		
	T CORPORATION	PATEL, SUDHAKER B		
4000 MONR	TUAL PROPERTY DEPART ROE ROAD	ART UNIT	PAPER NUMBER	
CHARLOTTE, NC 28205			1624	
			DATE MAILED: 11/25/2003	10

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	on No.	Applicant(s)			
Office Action Summary		10/085,3		MEUDT ET AL.			
		Examine		Art Unit			
	The MAN INC DATE of this communication		B. Patel, D.Sc.Tech.	1624			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Peri d for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)🛛	Responsive to communication(s) filed on	24 October 200	<u>)3</u> .				
2a)□ <sup>-</sup>	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
5)□ ( 6)⊠ ( 7)□ (	4) ☐ Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) 5 and 9 is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-4,6-8 and 10 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120  12) △ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) △ All b) ─ Some * c) ─ None of:  1. △ Certified copies of the priority documents have been received.  2. ─ Certified copies of the priority documents have been received in Application No  3. ─ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  13) ─ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  37 CFR 1.78.  a) ─ The translation of the foreign language provisional application has been received.  14) ─ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.							
Attachment(							
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-94 ation Disclosure Statement(s) (PTO-1449) Paper N			(PTO-413) Paper No(s). <u>10</u> . : atent Application (PTO-152)			

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### **DETAILED ACTION**

#### Election/Restrictions

- 1. Applicant's election of First recited process for Formula (I) with traverse of Invention of Group I in Paper No. 9 dated 10/24/03 is acknowledged. The traversal is on the ground(s) that the same is not proper without providing any reasons. This is not true, because examiner has already explained in the earlier office communications paper # 6, and # 8 dated 8/12/03 and 9/26/06 respectively by informing the applicants that the inventions are related not only to multiples of compounds (heterocyclic as well as non-heterocyclic), but also to different processes.
- 2. Process of Group I and Process of Group II employ different ratios of reactants and different process conditions to make the final products which are old, and are falling in U.S. PatentClassification System Class 568. In view of the recent Ochiai decision (37 USPQ 2d 1127) patentability of process claims is not only based on the nature of the reaction but also on the structure of the products and reactants employed. Thus art which may rander Group II old or obvious would not necessarily do the same for Group I.
- 3. Additionally, applicants desired, rejoinder of the compounds of Formulae I & II wherein X, Y, Z are carbons i.e. phenyl ring. This is not possible because as explained earlier, the compounds and processes for the Formulae (I) and (II) are different.

  Formula (I) compounds are Boronic acid compounds having 1:1- ratio of Boron to phenyl ring whereas Formula (II) compounds are Borinic acid compounds having 1:2-ratio of Boron to phenyl ring.

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4. It is believed that the instant application is related to different processes of making different compounds. Therefore, although the compounds fall in a single class e.g. 568, they are not believed to be made by the same process. Presence of reactive groups involving Phosphorous, Silicone, Sulfur atoms will intwerfere during the process of metalation with Li of haloaryl(s) as well as halogenated Hetero-rings as claimed herein. Prior art(s) discloses that different reaction conditions are necessary with different molar ratios, different addition of raw materials at different rates together with variations in temperatures for synthesis as well as hydrolysis to the Boronic acids and Borinic acids as claimed herein. Preferential reaction of lodo-substituted rings with Li do occurs. See rejections bellow in references recited.

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5. Preliminary search for Fluorophenyl and Lithium and synthesis and one pot process itself generated 1168461 hits, and the search for Fluorophenyl and Boronic acid generated 607817 hits.

As regards to multiples of compounds formed following hits are generated:

6. When one of X,Y,Z is N and the rest are Carbons, i.e. class <u>546, Pyridine</u> core the number of hits are:168; when the combination <u>is 1,2-diazine, i.e. class 544</u>, the hits are: 526; when the combination is <u>1,3-diazine i.e. pyrimidine, class 544</u>, the number of hits are:1388; when the combination is <u>triazine, class 544</u>, the number of hits are:499. Note, in class 546 i.e. pyridine it self, when Boron is present, the number of hits are 307, when Silicone is present, the number of hits are 847, and when phosphorous is present, the number of hits are 848. Therefore, although the class of compounds is the same, the searches by way of subclasses are different. Thus, it is this additional time

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required for a through and complete search that is time consuming and burdensome to examiner.

- 7. Based on above considerations, and the fact that applicants did not disclose the species as required by earlier communication(s), examiner urged applicants for providing a single species from the working examples. **See interview summary** enclosed with this communication.
- 8. Applicants have elected invention of Group I, drawn to claims (in part) 1-4,6-8,10 related to First recited process of making Formula (I) compounds related to Boronic acids.i.e. 1:1-ration of Boron to Phenyl without Phosphorous and Silicone. Applicants have also elected species of Example 1 as recited in page 11 of the specification (= Preparation of phenyl boronic acid).
- 9. Applicants are reminded of the election of species guidelines provided in MPEP 803.02, which are followed for examination.

Applicants' invention of Group I and the elected species of Example 1 have following meanings in the generic Formula (I) of claim 1.

X,Y,Z all are = Carbon atoms:

R1' to R5' substituents = H, C1-C8-alkyl, F, fluorinated alkyls,alkoxy.

Search was carried out with variables of species for the Formula (I) of generic claim 1 as exactly defined as above.

Initial search with above definitions of the variables revealed prior art(s). See rejection(s) bellow.

As per the guidelines stated above, the examination was limited to compounds of Formula (I). Claims 5,9 are withdrawn from further consideration by the examiner, as the same constitute non-elected subject matter.

Upon further review of the application, it is also believed that the working Examples included most of the Examplesare related to Formula(I) wherein X,Y,Z are carbons and R1-R5' are H only. Therefore, all values of the substituents R1' to R5' other than H, namely, phenyl, aryl, heteroaryl (= except furane), Salkyl, P(phenyl)2, P(aryl)2, P(alkyl)2 are withdrawn from consideration. Additionally, all other than stated above meanings of variables of Formula (I) of claim 1 are also withdrawn from

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consideration. Since claims1-4,6-8,10 link with other inventions, this application will be examined bearing in mind the subject matter related to invention of Group I and the species of Example 1 as elected by the applicants only. 37 CFR 1.142(b).

This application has been found to contain more than one invention. Therefore, the requirement for restriction/election is still deemed proper, and is made FINAL. First action on merits follows.

#### Information Disclosure Statement

10. The information disclosure statement (IDS) submitted on 5/3//02 as paper # 3 is being considered by the examiner. Signed copy of PTO Form 1449 is enclosed with this communication for applicants' record.

### Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 12. Claims1-4, 6-8,10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- (A). Claim 1 recite a single process of making compounds of Formulae (I) and (II) as Boronic and Borinic acids respectively. All the examples of the specification in pages 11 –13 disclose only Boronic acids and not Borinic. This will raise additional issues related to enable ment under 35 U.S.C. 112 paragraph first. Correction is required.
- (B). Claim recites variables R1' to R5' as: "Aryl, heteroaryl(substituted where applicable)". The claim 1 remains silent about the what is exactly excluded from these meanings. The exact number and make up of heteroaryl is not disclosed together with exact and definite ring size actually used in the working examples. Correction is required. In re. Sus et al., 135 USPQ 301; In re Lund et al., 153 USPQ 625.
- ( C ).Claim 1 recites(where applicable):" R1' to R5' variables as H, CH3, straight-chain or branched C1-C8 alkyl. It is confusing to read C1 alkyl as branched. Correction is required.
- (D). Claim 1 recites variables R1' to R5' as:" c(C1-C5 alkyl). This is not possible because valence of Carbon atom C is not fully satisfied. Correction is required. (E). Claim 1 recites R1' to R5' variables as:" (OC1-C5alkyl) as well as C1-C5-alkoxy-". This is duplication of meanings. Correction is required.

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(F). Claim 10 which is related to hydroluysis of the Bron complexex with 2.5 % HCL i.e. mineral acid and a further step of purifying the compounds by precipitation, filtration and vacume drying of the solid. Accordingly, the corrections are required.

### Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 14. Claims1-4,6-8,10 which are related to method of making the compounds, a are rejected under 35 U.S.C. 102(b) as being anticipated by Ivanov et al ( Doklady Bolgarskoi Akademi Nauk, 10/1,53-6(1957), also cited as Chemical Abstract DN 52:29887).
- 15. Ivanov teaches the making of organolithium compounds(RLi = PhLi) by reacting Aryl halide, Rx with ET2O and finely divided Li as claimed herein.

#### Claim Rejections - 35 USC § 103

- 16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. Claims 1-4,6-8,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Washburn et al( Adv. In chem. Ser., 23, 102-28(1959), also cited as Chemical Abstracts DN 54:34015) as applied to claims above, and further in view of Rocca et al( Chemical abstracts DN 120:134231, also cited as J. Org. Chem. 58/27,7832-8(1993)). The ref. Washburn teaches making of phenyl boronic acids from p-CIC6H4MgBr.

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Washburn differs from the instant process by using Mg, and one of instant R1' to R5' having a hchlorine atoms instead of F as claimed herein.

The other ref. Rocca et al teaches metalation of iodopyridine, 3-fluro-4-iodopyridine, 2-chloro-3-iodopyrindine with Li metal at low temperature.

However, one skilled in art would be motivated to try out various combinations involving different chemical structures obtained by varying nature and position of different halogens including starting chloro substituted, and non-heterocycles(=phenyl or ary rings) in the Washburn's process. The prior art(s) do teach: (1). Making of Lithium aryls & hydrolysis of organo-metallic boron complexes to get Boronic acids.

18. Claims 1-4,6-8,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosinger et al (GB 906145, also cited as Chemical Abstracts DN 58:14982) as applied to claims above, and further in view of Ivanov et al (Doklady Bolgarskoi Akademi Nauk, 10/1,53-6(1957), also cited as Chemical Abstract DN 52:29887).

Rosinger teaches making of aryl boronic acid. See Example 1 in lines 40-65 in page 3. Risinger differ from the instant process by using Mg, and the Boron complex is hydrlysed with 20% sulduric acis instead of 2.5% HCL as recited herein.

The other reference Ivanov teaches the making of organolithium compounds(RLi = PhLi) by reacting Aryl halide, Rx with ET2O and finely divided Li as claimed herein.

However, one skilled in art would be motivated to try out various combinations involving different chemical reagents by charging Li for Mg or by varying the different variables of the aryl ring as recited herein. The prior art(s) do teach: (1). Making of organo-lithium compounds and also making of Boron complexes (2). Use of mineral acids for hydrolysis.

19. Claims 1-4,6-8,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosinger et al( GB 906145, also cited as Chemical Abstracts DN 58:14982) as applied to claims above, and further in view of Huang et al( Chemical Abstract DN 131:144631, also cited as Wuhan Daxue Xuebao, Ziran Kexueban,45/2,160-164(1999)).

As discussed earlier Rosinger teaches making of aryl boronic acid. See Example 1 in lines 40-65 in page 3. Rosinger differ from the instant process by using Mg, and the Boron complex is hydrolysed with 20% sulfuric acis instead of 2.5% HCL as recited herein.

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The other reference Huang teaches the making of organolithium compounds by using Li insdead of Mg, and Huang has prepared 5-methyl-2-furanyl and 2-benzofuranyl boron compounds as Boronic acid, borinic acids and Borane derivatives.

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However, one skilled in art would be motivated to try out various combinations involving different chemical reagents by charging Li for Mg or by varying the different variables of the aryl ring, and replacing heterocycle by aryl ring as recited herein. The prior art(s) do teach: (1). Making of organo-lithium compounds and also making of Boron complexes (2). Use of mineral acids for hydrolysis.

- 20. A combination of two previously known steps is obvious when the product produced has properties taught by the prior art(s), in the absence of interaction between the steps, In re Fortess 152 USPQ 13.
- 21. Claiming of a new process by combining existing arts for making prior art known compounds with known property, which is inherently present in the prior art(s), does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.
- 22. It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989). See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by prior art" regardless to the properties disclosed in the inventor's application.
- 23. All this is especially considered so in the absence of timely, verified, comparative data, commensurate in scope to the claims sought, clearly and convincingly proving obvious ness over the art(s) as applied above. If applicants intend to rely on unusual or unforeseen results demonstrate patentability, attention is drawn to MPEP 716. It is also pointed out that arguments of patentability to differences either not in, or not made clear by, claim language will be of no avail as it is the claims, per se, that are the measure of the invention.
- 24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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#### Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached between 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

Sudhaker B.Patel, D.Sc.Tech.

November 22, 2003.

MUKUND SHAH SUPERVISORY PATENT **EXAMINER ART UNIT 1624** 

JOHN M. FORD PRIMARY EXAMINER

**GROUP**